UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,160	10/06/2003	Eli Sprecher	26465	5543

7590 04/09/2007

Martin D. Moynihan
PRTSI, Inc.
PO Box 16446
Arlington, VA 22215

EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	**PAPER NUMBER**
1657	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary	**Application No.** 10/678,160	**Applicant(s)** SPRECHER ET AL.	
	Examiner Dr. Kailash C. Srivastava	**Art Unit** 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2007*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,17 and 22* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1,7,17 and 22* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date *12/13/2006*.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Request for continued examination (i.e., RCE) under 37 CFR §1.114, including the fee set forth in 37 CFR §1.17(e), was filed in this application on 08 January 2007 after a Final action was mailed 06 October 2006. Since this application is eligible for continued examination under 37 CFR §1.114, and the fee set forth in 37 CFR §1.17(e) has been timely paid, the finality of the previous Office action mailed 06 October 2006 has been withdrawn pursuant to 37 CFR §1.114. Applicants' submission filed 06 October 2006 has been entered. Accordingly an RCE has been established and the action on RCE follows.

2. Applicants' responsive Amendment filed 08 January 2007 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

3. In view of remarks and amendment filed 08 January 2007, obviousness rejection to Claims 1, 7, 17 and 22 under 35 U.S.C. §103(a) over combined teachings from Blaschuck et al. (U.S. Patent 6,683,048 B1) in view of Stedman's Medical Dictionary (27th Edition, 2002. Williams and Wilkins, Baltimore, http://www.thomsonhc. com/pdrel/librarian/ PF Default ActionId/pdrcommon. Stedmans) in the Office Action mailed 06 October 2006 is hereby withdrawn.

4. The Art Unit Location to which your application has been assigned at the United States Patent and Trademark Office (i.e., USPTO) is changed to Art Unit 1657. To aid in correlating any papers for this application, all further correspondence regarding this application (i.e., 10/678,160) should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

CLAIMS STATUS

5. Claims 2-6, 8-16, 8-21 and 23-84 have been cancelled.

6. Claims 1, 7, 17 and 22 have been currently amended.

7. Claims 1, 7, 17 and 22 are pending and are examined on merits.

Information Disclosure Statement

8. Applicants' Information Disclosure Statement (i.e., IDS) filed 13 December 2006 is acknowledged, entered, have been made of record and considered. Accordingly, Examiner-initialed form 1449 is enclosed with this Office Action.

Claim Rejections - 35 U.S.C. §112

9. The following is a quotation of the first paragraph of 35 U.S.C. §112:

> ***The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.***

10. Claims 1,7,17 and 22 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession; at the time the invention was made, of the specific subject matter claimed. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude, "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T] he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co. the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Fiers, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279,.284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or sub-combinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

MPEP §2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP §2163 does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitutes a sufficient number of representative species, the courts have indicated what does not constitute a representative number of species to adequately describe a broad generic. In Gostelli, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are:(1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." (MPEP §2163).

In the instant case, the claims are drawn to methods of identifying a specific peptide molecule that will specifically modulate (i.e., enhance or inhibit) P-Cadherin and if said molecule specifically inhibits P-Cadherin, said method also identifies a hair growth inhibitor which is the peptide molecule inhibiting P-Cadherin. The claimed invention is analyzed according to following description for compliance with the written description requirement.

(a) Level of skill and knowledge in the art:

At least a Bachelor Degree in biochemical engineering, biochemical genetics, biochemistry, biology, biophysics, chemical engineering, chemistry, environmental engineering, environmental science and technology, enzymology, genetics, immunobiology, immunochemistry, immunology, microbiology, molecular biology, pharmaceutical sciences and pharmacology.

(b) Partial structure:

The specification repeatedly recites about the identification of a modulator (i.e., inhibitor) or enhancer) molecule (e.g., See Pages 9-17) but does not describe an y specific method to identify either a modulator of P-Cadherin or an inhibitor of hair growth aside from describing the family history of four families having individuals with congenital deficiencies in their specific chromosomes.

(c) Physical and/or chemical properties:

The physical and chemical properties of a P-Cadherin modulator molecule have been sporadically and in details (e.g., Page 9) have been described.

(d) Functional characteristics:

The specification only provides a discussion that P-Cadherin modulator molecule be either an enhancer, or inhibitor of the P-Cadherin. Additionally, there is mention of inhibiting hair growth. However, within Pages 1-51 of the specification, there is no clear, concise, to the point discussion or elaboration of structure function description of components required for said identification, or a step-by-step method to identify said modulator of P-Cadherin or said hair-growth inhibitor molecule. If there is one, applicants should clearly show said description on record.

(e) Method of making the claimed invention:

Despite providing a limited guidance to all the above four written description factors, the descriptive specification as currently presented does not have a clear showing of a step-by step method including components/composition useful for said method to identify either a modulator (i.e., inhibitor or enhancer of P-Cadherin) or a hair-growth inhibitor.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad genus. The possible variations are enormous to any class of polypeptides. Since the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the claimed P-Cadherin. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of identifying methods for P-Cadherin.

While clearly mentioning the background and other pertinent information including advantages of such a P-Cadherin modulator molecule as a pharmaceutical/cosmetic application, the specification as currently presented is devoid of a description of a method to identify claimed peptide molecule that is the modulator for P-Cadherin or inhibitor for hair growth.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline [e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

11. Claims 1,7,17 and 22 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with those claims.

The methods of identifying a specific peptide molecule that will specifically modulate (i.e., enhance or inhibit) P-Cadherin and if said molecule specifically inhibits P-Cadherin, said method also identifies a hair growth inhibitor which is the peptide molecule inhibiting P-Cadherin. The claimed invention is analyzed according to following description for compliance with the written description requirement.

From the record of the present written disclosure, the specification, gives a detailed description about a method to identify a peptide molecule that is a modulator (i.e., enhancer, or inhibitor) of P-Cadherin and further, said molecule is also inhibitor of hair growth and application of said molecule in pharmaceutical and cosmetic industry. However, said detailed description does not clearly and concisely describe a method to identify said peptide molecule, wherein said method will be method to directly identify a P-Cadherin modulator.

A person having ordinary skill would not be able to practice the invention because undue experimentation will be required to obtain the claimed method discussed *supra* due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) as illustrated below.

(a) Quantity of Necessary Experimentation

Since the specification, (see Pages 9-16 and 18-51) does not point out the precise step necessary to identify a peptide molecule that is modulator for P-Cadherin, a person of skill will have to perform a number of experiments to define each and every parameter/step as well as the components necessary in said steps to develop a method to identify a peptide molecule that is a modulator of P-Cadherin and simultaneously an inhibitor of hair growth.

(b) Limited Amount of Guidance

The specification as currently presented does not provide a clear-cut guidance to "identify a peptide molecule that is modulator for P-Cadherin as well as an inhibitor of hair growth.

(c) Limited Number of Working Examples in the Specification

The specification does not provide examples of steps to "identify a peptide molecule that is a modulator for P-Cadherin and an inhibitor for hair growth.

(d) Nature of the Invention

The invention is particularly drawn to a method to "identify a peptide".

(e) State of the Prior Art

From the description of the prior art given in the specification, there is contemplation of a method to identify a peptide having the structure function integration to be a modulator of P-Cadherin and an inhibitor of hair growth (See, e.g., specification Page 9).

(f) Relative Skill Level of those in the Art

At least a Bachelor Degree in biochemical engineering, biochemical genetics, biochemistry, biology, biophysics, chemical engineering, chemistry, environmental engineering, environmental science and technology, enzymology, genetics, immunobiology, immunochemistry, immunology, microbiology, molecular biology, pharmaceutical sciences and pharmacology.

(g) Predictability or Unpredictability in the Art

In the instant case, since a method to identify a peptide having the structure function integration to be a modulator of P-Cadherin and an inhibitor of hair growth (See, e.g., specification Page 9) is disclosed, it can not be predicted that said inhibitor (s) would have the required properties/function or activity, because unless supported with illustrative experimental evidence, biological responses are unpredictable. Thus, information obtained under one set of detrimental parameters may not be extrapolated for another set of parameters or specific conditions.

(h) Breadth of the Claims

Each of Claims 1, 7, 17 and 22, especially Claims 1 and 17 cover a fairly broad technical area.

12. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> ***The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.***

13. Claims 1, 7, 17 and 22 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The recitation "capable" renders Claims 1 and 17 indefinite because this recitation in and by itself denotes a futuristic event. The metes and bounds of the claimed subject matter are not clearly defined. Please define the metes and bounds of the term "capable".

All other claims depend directly from the rejected claim (e.g., Claims 1 and 17) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections Under 35 U.S.C. § 103(a)

14. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> ***A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.***

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § *102*(f) or (g) prior art under 35 U.S.C.§ 103(a).

16. Claims 1, 7, 17 and 22 are rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from Hirai et al. (Expression and Role of E- and P- Cadherin Adhesion Molecules in Embryonic Histogenesis. II. Skin Morphogenesis. 1989. Development, Volume 105, Pages 271-277) in view of Brenner et al (U.S. Patent 6,787,136 B1).

Claims recite a method to identify a peptide molecule that is a modulator specifically to P- Cadherin and further a method to test said P-Cadherin modulator or inhibitor as a hair growth inhibitor. Thus, Said method comprises identifying a P-Cadherin modulator, wherein said P-Cadherin modulator is a peptide. Claims also recite a method to identify a hair growth inhibitor. Said method comprises identifying a P-Cadherin inhibitor, wherein said P- Cadherin inhibitor is a peptide.

Regarding Claims 1, 7, 17 and 22, Hirai et al. teach a method to identify P-Cadherin inhibition by antibodies specific to P-Cadherin through monitoring expression of E – and P-Cadherin in the surface epidermis and vibrissa follicles of cultured mouse upper lip skin. The skin was cultured in absence and presence of a monoclonal antibody specific to P-Cadherin and also in the mixtures of P-cadherin specific and E-Cadherin specific antibodies. While control cultures exhibited normal skin morphology, those grown in presence of P-Cadherin specific monoclonal antibodies, the hair follicle were deformed (See Abstract, at Page 271, Column 1, Line24 to Column 2, Lne17; Page 271, Column 2, Lines 37-47). Note that Hirai et al. teach each and every element of the invention claimed in Claims 1, 7, 17 and 22 because they have found a method to identify a modulator of P-Cadherin that is also a peptide. Since applicants do not claim the length their claimed peptide, a monoclonal antibody is considered a peptide molecule. Said peptide being a monoclonal antibody specific to P-Cadherin, specifically modulates P-Cadherin and is also inhibitory to the hair follicles, i.e., inhibits hair growth. Hirai et al's teachings might be argued as making the incident invention indirectly obvious but Brenner et al. supplement Hirai et al's teachings by clearly stating " screening assays for identifying pharmaceutical lead compounds capable of modulating cellular functions of Cadherin 11. and said cadherin-11 inhibitory molecule is an antibody (Abstract, Lines 1-5; Column 3, Lines 18-22; Column 4, Lines 45-62 and Column 57, Lines 50-54).

A person of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings from Hirai et al. of antibody mediated inhibition of P-Calderon and of hair follicle inhibition with those of an assay method that Brenner et al. teach, because both Hirai et al. and Brenner et al. teach methods to identify a peptide molecule that is modulator of P-Cadherin, wherein said P-Cadherin inhibitor is a hair follicle inhibitor and Brenner t al teach an assay method to screen for a peptide molecule that is modulator, i.e., inhibitor of P-Cadherin.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the Hirai et al's teachings of identifying a P-Cadherin modulating peptide molecule that is also a hair follicle inhibitor with the assay methods from Brenner et al. because Hirai et al. teach identification of a P-Cadherin inhibitor that is also an inhibitor of hair follicle and Brenner et al. teach a method to assay a peptide modulator/inhibitor of P-Cadherin. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above-cited references before him.

From the teachings of the cited references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

17. For reasons aforementioned, no Claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1657
(571) 272-0923

March 31, 2007

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 128/1657